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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,887	12/11/2001	Geoffrey W. Krissansen	8654/2072	2382

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EXAMINER

YAO, LEI

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/014,887

Applicant(s)

KRISSANSEN ET AL.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 10, 11, 15, 18, 19, 23, 26, 27, 31, 34, 35, 39, 42, 43, 47 and 48-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-9, 12-14, 16, 17, 20-22, 24, 25, 28-30, 32-33, 36-38, 40, 41, and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

Art Unit: 1642

The art unit and examiner of your application in the USPTO have been changed. To aid in correlation any paper for this application, all further correspondence regarding this application should be directed to Art Unit 1642, Examiner Lei Yao.

## **DETAILED ACTION**

### **Election of Restriction**

Applicant's election of Group I in the reply filed on 09/16/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of an analog of XAA in the reply filed on 01/24/2005 is acknowledged.

Claims 5-7 and 48-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 10, 11, 15, 18, 19, 23, 26, 27, 31, 34, 35, 39, 42, 43, and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-55 are pending. Claims 1-4, 8-9, 12-14, 16, 17, 20-22, 24, 25, 28-30, 32-33, 36-38, 40, 41, and 44-46 are examined on merits to the extent they are drawn to the elected species of an XAA analog.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 8-9, 12-14, 16, 17, 20-22, 24, 25, 28-30, 32-33, 36-38, 40, 41, and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedley et al (Cancer Research, Vol, 56, p3293-3300, 1996).

Claims 1-3 are drawn to a method of treatment for a mammal with tumor, comprising the administration to said mammal of an immunotherapeutic agent in combination with a tumor growth-restricting agent, either of which alone would be ineffective in retarding or eradicating an tumor burden. Claim 4 is drawn to a method of potentiating the activity of a tumor growth-restricting agent against tumors which comprises the step of pre-administering to a patient an amount of an immunotherapeutic agent which, upon subsequent administration of said tumor growth restricting agent, acts in combination with said tumor growth restricting agent to eradicate an advanced or large tumors. Claims 8-9, 12-14, 16, 17, 20-22, 24, 25, 28-30, 32-33, 36-38, 40, 41, and 44-46 embody the claims 1-4, wherein the tumor growth-restricting agent is DMXAA, wherein immunotherapeutic agent is administered 12-48 hours prior to the tumor growth restricting agent, or wherein the method further includes the administration of an additional tumor growth-restricting agent.

Pedley et al disclose a method of treating mice with tumor using an immunotherapeutic agent, a radio-labeled antibody, in combination with a tumor growth-restricting agent, DMXAA. Pedley et al also disclose a method of treating said mice with the antibody in combination with DMXAA and further adding a tumor growth-restricting agent, serotonin. Pedley et al disclose that the mice with tumor are administered with the radio-labeled antibody or DMXAA alone or in combination of both, in which DMXAA is given at 48 hours after administration of the said antibody. Pedley et al disclose that treating the mice with tumor with either the immunotherapeutic agent or the tumor growth-restricting agent is ineffective in retarding or eradication the tumor burden. Pedley et al disclose that the tumor is eradicated by the combination therapy of the radio-labeled antibody and DMXAA (p 3295, column I, paragraph 1 and figure 4). Pedley et al also disclose that the tumor is eradicated by the combination therapy with the radio-labeled antibody in combination of DMXAA and further adding serotonin at 48 and 72 hours after administering the antibody (p3294, column I, paragraph 6, p 3295, column II, paragraph 2 and figure 5).

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Pedley et al teach that serotonin is also given in addition to the two different agents, DMXAA and the antibody. Although Pedley et al do not disclose that serotonin is a "tumor-restricting agent", Zhou et al., at the abstract teach that serotonin has an anti-angiogenic effect. Note page 2, paragraph 7 of the specification for the definition of "tumor restriction agent". Therefore, serotonin meets the definition of "tumor restricting agent" at page 2, paragraph 7 of the application.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8a -4.30pm, Monday to Friday.

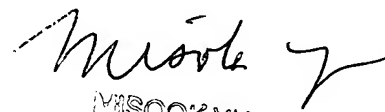
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.  
Examiner  
Art Unit 1642

LY

  
MISOOK YU  
PATENT EXAMINER